



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Re: BeneFIXTM
Docket No. 97E-0168

The Honorable Q. Todd Dickinson
Deputy Assistant Commissioner for
Patent Policy and Projects
Office of the Assistant Commissioner for Patents
U.S. Patent and Trademark Office
Crystal Park Building 2, Suite 919
Washington, DC 20231

APR 13 1999

Dear Commissioner Dickinson:

This is in regard to the patent term extension application for U.S. Patent No. 5,171,569 filed by British Technology Group Limited under 35 U.S.C. § 156. The patent claims the human biological product BeneFIXTM (coagulation factor IX (Recombinant)), product license application PLA 96-1048.

In the August 4, 1998, issue of the Federal Register (63 Fed. Reg. 41579), the Food and Drug Administration published its determination of this product's regulatory review period, as required under 35 U.S.C. § 156(d)(2)(A). The notice provided that on or before February 1, 1999, 180 days after the publication of the determination, any interested person could file a petition with FDA under 35 U.S.C. § 156(d)(2)(B)(i) for a determination of whether the patent term extension applicant acted with due diligence during the regulatory review period.

The 180-day period for filing a due diligence petition pursuant to this notice has expired and FDA has received no such petition. Therefore, FDA considers the regulatory review period determination to be final.

Please let me know if we can provide further assistance.

Sincerely yours,

Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs

cc: M.C. Meinert, Esq.
Genetics Institute, Inc.
Legal Affairs
87 Cambridge Park Drive
Cambridge, MA 02140

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Date: **APR 13 1999**

From: **Brian J. Malkin, Associate Director for Patents and Hearings
Health Assessment Policy Staff (HFY-20)**

Subject: **Patent Term Restoration Application
for BeneFIX™**

To: **Dockets Management (HFA-305)**

Attached is a letter to the Patent Term Office for the above mentioned drug under the Docket Number **97E-0168** stating that this particular patent is eligible for regulatory review. The Patent Number is **5,171,569**. Please place this recent correspondence in the appropriate file.

If you have any questions, please contact me at 827-6620. Thank you for your assistance.